DEC 0 5 2001

k013688

Special 510(k) Summary of Safety and Effectiveness: OSS and Opus Rods – Use with Xia Spinal System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	November 6, 2001

Device Identification

Proprietary Name:	Xia Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis, 21 CFR 888.3050 Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060 Pedicle Screw Spinal System 21 CFR 888.3070

Predicate Device Identification

The Xia Spinal System was determined substantially equivalent via 510(k)s K982494, K984251, K001319, K002505 and K012027. The Xia Screws were cleared for use with the Multi-Axial Cross Connector via 510(k) K002505. The Rods for the Osteonics® Spinal System (OSS) were determined substantially equivalent via 510(k) K951725. The Rods for the Opus Spinal System were determined substantially equivalent via 510(k) K990922. This submission is intended to allow the use of the predicate OSS and Opus Rods with the predicate Xia Spinal System.

Description of Device Modification

The submission involves no change to the components themselves. This submission covers use of predicate OSS and Opus 6 mm diameter Rods with the predicate Xia Spinal System.

Intended Use:

The Rods from the Osteonics® Spinal System and Opus Spinal System are intended to be used with the components of the Xia Spinal System.

Indications for Use:

The Xia Spinal System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spinal System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the XIA Spinal System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spinal System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

Statement of Technological Comparison:
Construct fatigue testing demonstrates comparable mechanical properties of the subject Xia Spinal System with Ti-6Al-4V alloy (Opus or OSS) Rods to other predicate constructs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Karen Ariemma
Howmedica Osteonics Corp.
Regulatory Affairs Specialist
59 Route 17
Allendale, New Jersey 07401

DEC 0 5 2001

Re: K013688
Trade Name: Xia Spine System
Regulation Number: 21 CFR 888.3050, 888.3060, and 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, and Pedicle screw spinal system.
Regulatory Class: II
Product Code: MNH, KWP, KWQ, and MNI
Dated: November 6, 2001
Received: November 7, 2001

Dear Ms. Ariemma:

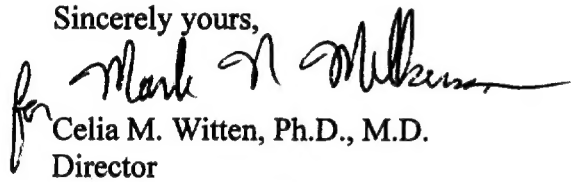
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013688

Device Name: Xia Spinal System

The 6 mm diameter rods from the Osteonics® Spinal System and Opus Spinal System are intended to be used with the other components of the Xia Spinal System.

Indications For Use:

The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013688